UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

JANSSEN PRODUCTS, L.P., and PHARMA MAR, S.A.,

Plaintiffs,

v.

EVER VALINJECT GMBH, NEXUS PHARMACEUTICALS, LLC, SHANGHAI HAOYUAN CHEMEXPRESS CO., LTD, MEDCHEMEXPRESS LLC, and RUYUAN HEC PHARM CO., LTD.,

Defendants.

Case No. 24 C 7319

Judge Sunil R. Harjani

MEMORANDUM OPINION AND ORDER

This pharmaceutical patent infringement case arises out of Defendant EVER Valinject GmbH's submission of a New Drug Application (NDA) to the United States Food and Drug Administration for approval to sell a generic version of Plaintiff Pharma Mar, S.A.'s Yondelis® drug product (the "EVER NDA Product"). Yondelis® is a drug used to treat rare forms of soft-tissue cancer. Plaintiffs assert two patents in this case: United States Patent No. 8,895,557 (the '557 Patent) and United States Patent No. 7,420,051 (the '051 Patent). Plaintiffs allege that EVER's submission of its NDA to the FDA constitutes infringement of at least claims 1-8, 11-20, and 22-26 of the '557 Patent. Plaintiffs also seek declaratory judgments that: (1) Defendants' commercial manufacture, use and/or sale of the EVER NDA Product prior to the expiration of the '557 Patent would infringe, contribute to the infringement of, and/or induce the infringement of at least claims 1-8, 11-20 and 22-26 of the '557 Patent under 35 U.S.C §§ 271(a), (b) and/or (c), under the doctrine of equivalences, and (2) Defendants' importation, use, sale, and/or offer for sale of the EVER NDA Product prior to the expiration of the '051 Patent would infringe, contribute to

the infringement of, and/or induce the infringement of one or more claims of the '051 Patent under 35 U.S.C. § 271(g).

Defendants have filed three motions to dismiss the consolidated complaint. Defendants Shanghai Haoyuan Chemexpress, Ltd. ("SHC"), Medchemexpress LLC ("MCE"), and Ruyuan HEC Pharm Co., Ltd. ("Ruyuan") move pursuant to Federal Rule of Civil Procedure 12(b)(2) to dismiss the claims against them for lack of personal jurisdiction. MCE moves to dismiss under Rule 12(b)(3) for improper venue. All Defendants move to dismiss Count III for lack of subject matter jurisdiction due to non-ripeness pursuant to Federal Rule of Civil Procedure 12(b)(1). All Defendants also move to dismiss the Complaint for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). For the following reasons, the motions to dismiss based on lack of personal jurisdiction are denied as to SHC and Ruyuan and denied as moot as to MCE. MCE's motion to dismiss for lack of venue is denied but MCE is severed from this suit, and the case as to MCE will be transferred to the United States District Court for the District of New Jersey. Defendants' Rule 12(b)(1) motions to dismiss for lack of jurisdiction as to Count III are granted. Defendants' motions to dismiss the Complaint pursuant to Rule 12(b)(6) are granted in part and denied in part.

DISCUSSION

Plaintiff Janssen Products, L.P. is a New Jersey partnership with its headquarters and principal place of business in Pennsylvania. Plaintiff Pharma Mar, S.A. ("Pharma Mar") is a Spanish corporation with a principal place of business in Madrid, Spain. Defendant EVER is based in Austria, Defendant Nexus Pharmaceuticals, LLC in Illinois, Defendant SHC in China, Defendant MCE in New Jersey, and Defendant Ruyuan in China.

Plaintiff Pharma Mar holds two patents on Yondelis®: the '557 Patent and the '051 Patent. The '557 Patent covers formulations containing trabectedin (the active ingredient in Yondelis®) along with a "disaccharide selected from sucrose, lactose, and a combination thereof." Doc. 73, Compl., Ex. at 27:57-29:12. The '557 Patent will expire on January 7, 2028. The '051 Patent covers methods of making trabectedin. The '051 Patent expires on January 21, 2026. Pharma Mar holds NDA No. 207953 for Yondelis®. Plaintiff Janssen holds an exclusive license to the '557 Patent and sells Yondelis® in the United States. The EVER NDA was filed with the FDA under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), seeking approval to market a version of Yondelis® before expiration of the Patents-in-Suits. The EVER NDA contained a Paragraph IV certification with respect to each of the Patents-in-Suit.[1]

I. SHC's and Ruyuan's Motions Regarding Personal Jurisdiction

The Court first considers Defendants SHC and Ruyuan arguments that dismissal is proper under Rule 12(b)(2) because the Court lacks personal jurisdiction over them.[2] Plaintiffs oppose these arguments, and in the alternative, requests leave to conduct jurisdictional discovery. In

[1] A generic manufacturer's paragraph IV certification claims that any listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). "Filing a paragraph IV certification . . . [i]s itself an act of infringement, which gives the brand an immediate right to sue." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 407 (2012); *see* 35 U.S.C. § 271(e)(2)(A). "If the brand-name patentee brings an infringement suit [under § 271(e)(2)(A)] within 45 days, the FDA then must withhold approving the generic, usually for a 30-month period, while the parties litigate patent validity (or infringement) in court." *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 143 (2013). A generic manufacturer "cannot receive final FDA approval during the 30–month stay period. Nevertheless, the FDA grants 'tentative approval' when it determines that the ANDA has satisfied the FDA's non-patent regulatory requirements and would receive final approval but for the 30–month stay." *In re Neurontin Antitrust Litig.*, 2009 WL 2751029, at *11 (D. N.J. Aug. 28, 2009) (citing 21 C.F.R. §§ 314.105(a); 314.107(b)(3)(v)).

[2] Plaintiffs and MCE also dispute whether this Court has personal jurisdiction over MCE. Because the Court finds below that venue is not proper in this District as to MCE, it need not reach MCE's personal jurisdiction challenges. *See Leroy v. Great Western United Corp.*, 443 U.S. 173, 180 (1979) ("[W]hen there is a sound prudential justification for doing so . . . a court may reverse the normal order of considering personal jurisdiction and venue."); *Amachree v. Barr*, 2019 WL 6467316, at *2 (N.D. Ill. Dec. 2, 2019) (same).

patent infringement suits, Federal Circuit law governs the personal jurisdiction analysis, while Seventh Circuit law governs jurisdictional discovery. *Univ. of Mass. v. L'Orèal S.A.*, 36 F.4th 1374, 1384 (Fed. Cir. 2022). On a motion to dismiss under Rule 12(b)(2) without an evidentiary hearing, the Court "must accept the uncontroverted allegations in [the plaintiff's] complaint as true and resolve any factual conflicts in the affidavits in [the plaintiff's] favor." *Apple Inc. v. Zipit Wireless, Inc.*, 30 F.4th 1368, 1374 (Fed. Cir. 2022); *Curry v. Revolution Labs., LLC*, 949 F.3d 385, 393 (7th Cir. 2020) (courts may consider extrinsic evidence in deciding a Rule 12(b)(2) motion). No party has requested an evidentiary hearing on the facts relevant to personal jurisdiction, so Plaintiffs need only make a prima facie showing that defendants are subject to personal jurisdiction. *Autogenomics, Inc. v. Oxford Gene Tech. Ltd.*, 566 F.3d 1012, 1017 (Fed. Cir. 2009); *see also Purdue Research Found. v. Sanofi-Synthelabo, S.A.*, 338 F.3d 773, 782 (7th Cir. 2003) (same). The prima facie standard requires less than proof by a preponderance of the evidence. *Genetic Veterinary Scis., Inc. v. LABOKLIN GmbH & Co. KG*, 933 F.3d 1302, 1309 (Fed. Cir. 2019).

Under Federal Rule of Civil Procedure 4(k)(1)(A), a district court has personal jurisdiction over a defendant in a patent case if that defendant would be "subject to the jurisdiction of a court of general jurisdiction in the state where the district court is located." Fed. R. Civ. P. 4(k)(1)(A). Whether personal jurisdiction exists involves two inquiries: "whether a forum state's long-arm statute permits service of process and whether assertion of personal jurisdiction violates due process." *Trimble Inc. v. PerDiemCo LLC*, 997 F.3d 1147, 1152 (Fed. Cir. 2021). "[T]he Illinois long-arm statute permits the exercise of personal jurisdiction to the full extent permitted by the Fourteenth Amendment's Due Process Clause." *Bilek v. Fed. Ins. Co.*, 8 F.4th 581, 590 (7th Cir. 2021) (internal quotes and citation omitted). Thus, the personal-jurisdiction analysis turns on

whether the exercise of personal jurisdiction would violate due process. *Elecs. For Imaging, Inc. v. Coyle*, 340 F.3d 1344, 1350 (Fed. Cir. 2003).

In arguing against personal jurisdiction, SHC and Ruyuan, both of which are Chinese corporations, submit that they: (1) have no physical office or physical presence in the State of Illinois or anywhere else in the United States; (2) are not registered to do business in Illinois; (3) do not own, rent, lease, or possess any real property in Illinois; (4) do not employ any Illinois residents; (5) do not maintain a mailing address or telephone listing in Illinois; (6) do not have any distributors or vendors located in Illinois; (7) do not have any distributors or vendors that sell or offer to sell any products or services in Illinois; (8) do not solicit business in Illinois; (9) do not have any customers in Illinois; (10) do not direct advertisements at Illinois or its residents; and (11) do not receive any revenue from Illinois or its residents. Doc. 87-1 ¶ 4; Doc. 97-1 ¶ 4.

Plaintiffs respond that the Court has specific jurisdiction over SHC and Ruyuan because each entity is a "submitter" of the EVER NDA. Doc. 73, Compl. ¶¶ 28, 43.[3] Specific jurisdiction "must be based on activities that arise out of or relate to the cause of action, and can exist even if the defendant's contacts are not continuous and systematic." *Grober v. Mako Products, Inc.*, 686 F.3d 1335, 1346 (Fed. Cir. 2012) (internal quotes and citation omitted). To determine whether a court can exercise specific jurisdiction over a nonresident defendant, a court considers whether: "(1) the defendant purposefully directed its activities at residents of the forum state, (2) the claim arises out of or relates to the defendant's activities with the forum state, and (3) assertion of

[3] Plaintiffs argue, in the alternative, that the Court may exercise personal jurisdiction under Rule 4(k)(2), which provides for "personal jurisdiction over a defendant if . . . the defendant is not subject to jurisdiction in any state's courts of general jurisdiction; and . . . exercising jurisdiction is consistent with the United States Constitution and laws." Fed. R. Civ. P. 4(k)(2). Because the Court finds that it may exercise specific jurisdiction over SHC and Ruyuan, the Court does not reach Plaintiffs' alternative argument about Rule 4(k)(2). *Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 127 F.4th 896, 908 n.3 (Fed. Cir. 2025).

personal jurisdiction is reasonable and fair." *Id.* (internal quotes and citation omitted). The first two factors comprise "minimum contacts," while the third factor ensures that any jurisdiction exercised "does not offend the traditional notions of 'fair play and substantial justice.'" *Apple*, 30 F.4th at 1375 (quoting *Burger King Corp. v. Rudzewicz*, , 476–77 (1985)). The plaintiff bears the burden of establishing minimum contacts under the first two factors. *Coyle*, 340 F.3d at 1350. If the plaintiff meets that burden, defendant must show that the exercise of jurisdiction over it is unreasonable. *Id.*

Applying the above factors, the Court concludes that it can exercise specific jurisdiction with respect to SHC and Ruyuan pursuant to the Federal Circuit's decision in *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 760, 762-63 (Fed. Cir. 2016). "[T]he submission of an ANDA . . . has a substantial connection with the forum state where the defendant plans to market its proposed drug[] in the forum state and the lawsuit is about patent constraints on such in-State marketing." *AbbVie Inc. v. Alvotech hf.*, 2021 WL 3737733, at *12 (N.D. Ill. Aug. 23, 2021) (Lee, J.) (internal brackets and quotes omitted) (quoting *Acorda Therapeutics Inc..*, 817 F.3d at 762-63 ("In our view, the minimum-contacts standard is satisfied by the particular actions Mylan has already taken—its ANDA filings—for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in Delaware.")); *see also Valeant Pharms. N. Am. LLC v. Mylan Pharms., Inc.*, 978 F.3d 1374, 1384 (Fed. Cir. 2020) ("We held [in *Acorda*] that submission with intent to distribute the generic product in a given state was sufficient for personal jurisdiction purposes."). Thus, "where the drug that is the subject of the ANDA will be marketed within the forum state, a defendant's ANDA filings are suit-related, and they have a substantial connection with the forum state because they reliably, non-speculatively predict forum state activities by the

submitter." *AbbVie Inc.*, 2021 WL 3737733, at *12 (internal brackets and quotes omitted) (quoting *Acorda*, 817 F.3d at 762).[4]

SHC and Ruyuan assert that they are not "submitters" of the EVER NDA because EVER physically submitted the NDA. Thus, according to SHC and Ruyuan, EVER is the only submitter of the NDA at issue. However, "[a]n entity . . . need not sign, prepare, or file an NDA to be a 'submitter.'" *Novartis Pharms. Corp. v. Handa Neuroscience LLC*, 2022 WL 610771, at *4 (D. Del. Mar. 1, 2022). An entity submits an NDA if it actively participates in the preparation of the ANDA and stands to benefit directly from the NDA by selling the generic product upon FDA approval. *Celgene Corp. v. Mylan Pharms. Inc.*, 17 F.4th 1111, 1129 (Fed. Cir. 2021); *In Re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 528-29 (Fed. Cir. 2012). Moreover, an NDA can have multiple submitters. *AbbVie*, 2021 WL 373773, at *8 ("*Parties* actively involved in preparing the ANDA are deemed to have submitted the ANDA, regardless of whether they are the named applicant . . . .") (emphasis added) (internal quotes and citation omitted).

The current record supports a prima facie case that SHC and Ruyuan are submitters of the EVER NDA. Initially, because an NDA can have multiple submitters, the fact that the Complaint refers to EVER as having submitted the NDA does not preclude other parties from having submitted it too. The Complaint also alleges that SHC has "participat[ed] in the preparation and submission of the EVER NDA." Doc. 73, Compl. ¶ 33; see *id*. ¶ 28 (SHC "act[ed] in concert with Defendants in the preparation and submission of the EVER NDA"). While this assertion is conclusory, the EVER NDA supports Plaintiffs' allegation that SHC was involved in preparing

[4] A Section 505(b)(2) NDA "is like an ANDA because the company need not produce all safety and efficacy data about the drug and because it must assure the FDA that its generic drug will not infringe the brand's patents," but differs "because the company must produce some data, including whatever 'information [is] needed to support the modification(s).'" *Fed. Trade Comm'n v. AbbVie Inc*, 976 F.3d 327, 339 (3d Cir. 2020) (quoting 21 C.F.R. § 314.54(a)).

the EVER NDA, which includes "participating in the drug's manufacture." *AbbVie*, 2021 WL 3737733 at *8 (internal brackets and quotes omitted); *see also Otsuka Pharm. Co., Ltd., v. Hetero USA, Inc.*, 2020 WL 6822971, at *2 (D. Del. Nov. 20, 2020) (holding that "whether the entity is a submitter depends on whether it is also going to engage in the commercial manufacture, use, or sale of the proposed generic product") (internal quotes and citation omitted). The EVER NDA indicates that SHC is involved in manufacturing and otherwise developing the EVER NDA Product. For example, the EVER NDA states that SHC is "[r]esponsible for the analysis and testing of GMP [Good Manufacturing Practice] starting materials, R&D and characterization analysis of Trabectedin API [active pharmaceutical ingredient], and analytical procedures validations, etc." Doc. 91-1 at 6. The EVER NDA represents that SHC's "manufacturing processes and controls ensure consistent production of the drug substance." *Id*. at 7; *see also id*. at 8 (SHC's Drug Master File ("DMF")[5] also contains "information pertaining to the description of the elucidation of structure and other characteristics of the drug substance"). Moreover, the EVER NDA contains a letter from SHC "authoriz[ing]" use of its DMF No. 36724 for trabectedin in the EVER NDA and the FDA's review of the information in the DMF when considering the EVER NDA. Doc. 91-2 at 2. Further, the NDA identifies SHC as the "Contact for Regulatory Correspondence with Health Authorities." Doc. 91-1 at 5. All of this supports a reasonable inference that SHC has been actively involved in preparing the EVER NDA.

Similarly, the Complaint specifically alleges that Ruyuan has "participat[ed] in the preparation and submission of the EVER NDA." Doc. 73, Compl. ¶ 45; *see id*. ¶ 43 (Ruyuan

[5] "A DMF is a confidential submission to the FDA that provides detailed information about the processes used to manufacture a drug." *Astellas US LLC v. Hospira, Inc.*, 2022 WL 17998229, at *2 (Fed. Cir. 2022). SHC is the holder of two DMFs: (1) "DMF No. 36724 for trabectedin," referenced in the EVER NDA; and (2) "DMF No. 36899 which . . . is directed to an intermediate and/or starting material for the manufacture of trabectedin, including for purposes of manufacturing the proposed EVER NDA Product." Doc. 73, Compl. ¶ 8.

"act[ed] in concert with Defendants in the preparation and submission of [] the EVER NDA"). The EVER NDA also supports that Ruyuan is participating in the EVER NDA Product's manufacture. For example, the EVER NDA lists Ruyuan, among other sites, under the header "Who manufacturers the drug substance?" Doc. 108-2 at 5. The EVER NDA states that Ruyuan is the manufacturing facility of the trabectedin drug substance and is "responsible for the manufacturing and release of the final trabectedin drug substance." *Id*. The EVER NDA lists Ruyuan, as well as SHC, as a "Quality Control Testing Site" and explicitly states that Ruyuan is "[r]esponsible for the analysis and testing of Trabectedin API final product release, stability studies, and analytical procedures validations, etc." *Id*. at 6. Considered together, these statements support a reasonable inference that Ruyuan has been actively involved in preparing the EVER NDA.

To controvert Janseen's allegations and the EVER NDA, SHC and Ruyuan produced the declarations of Dr. Kui Mei and Dezhang Lin, respectively. In his declaration, Dr. Mei asserts that SHC "has not acted, in concert or not, with any of the defendants named in the instant lawsuit with respect to any manufacturing, marketing, sale, or distribution of the proposed EVER NDA [] product in the State of Illinois." Doc. 87-1 ¶ 7. Lin attests that Ruyuan "has not operated in concert with or under the direction of any of the defendants named in the instant lawsuit with respect to the development and manufacture of the trabectedin API" or "with respect to the development, regulatory approval, commercial manufacture, marketing, [etc.] of the proposed EVER NDA Product for the United States market, including in the State of Illinois market." Doc. 97-1 at ¶ 7. Lin further attests that Ruyuan "has not [] acted in concert with any defendant in the preparation and submission of [] the EVER NDA that seeks FDA approval to market the proposed EVER NDA Product in the United States, including Illinois." *Id*. at ¶ 8. In light of the representations in the

EVER NDA with respect to SHC's and Ruyuan's involvement with the manufacturing of the EVER NDA Product and the minimal prima facie standard for evaluating personal jurisdiction, these conclusory assertions are inadequate to support SHC's and Ruyuan's argument that neither SHC nor Ruyuan is a submitter of the NDA at issue here. At this stage, all factual conflicts between the record and SHC's and Ruyuan's declarations must be resolved in Janseen's favor. *Polar Electro Oy v. Suunto Oy*, 829 F.3d 1343, 1347-48 ("Under th[e] prima facie standard, the court must resolve all factual disputes in the plaintiff's favor."); *see also Curry*, 949 F.3d at 393. Consequently, SHC's and Ruyuan's declarations renouncing involvement with the EVER NDA fail to overcome the statements from the actual NDA detailing their involvement in the drug's manufacture.

Further, the Court finds that Dr. Mei's statement that SHC "does not know or intend that the proposed EVER NDA [] product will be distributed or sold in Illinois" fails to defeat personal jurisdiction at this stage of the proceedings where there is no evidence that Defendants' carved out Illinois in seeking nationwide marketing authorization from the FDA. Doc. 87-1 ¶ 7; *Regeneron*, 127 F.4th at 910 (holding exercising personal jurisdiction does not require "affirmative evidence of [defendant] calling express attention to [the forum state] as a target market . . . . [T]here is simply no good reason, under the constitutional standard, for demanding such singling-out evidence."). Indeed, 'the purpose of [an] []NDA submission is to market a generic drug nationwide, including in [Illinois]." *Allergan, Inc. v. Teva Pharms.*, 2016 WL 1572193, at *3 (Apr. 19, 2016). SHC's and Ruyuan's active involvement in the preparation of the EVER NDA thus creates a reasonable inference that they intend to market the drug in Illinois. And Illinois is the state of incorporation and principal place of business of Defendant Nexus, the alleged "registered U.S. agent for the EVER NDA submission and marketing partner" for the EVER NDA Product.

Doc. 73, Compl. ¶ 7. Finally, the Court does not accept that a submitter finding requires that the additional submitter be an "affiliate," an "agent," or an "integrated/unitary entity of the unquestionable submitter," because it is just one factor to consider among many. Doc. 101 at 9; *see Rosuvastatin*, 703 F.3d at 528 (referring to "parent subsidiary" and "principal-agent" relationships as "factors," not requirements); *Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 338, 349 (D. Del. 2009) (that the "parties involved are in the same corporate family" is just a fact that "especially" supports submitter status).

In addition, the record supports that SHC and Ruyuan would benefit from the EVER NDA's approval. The Complaint alleges that "each of the Defendants will financially benefit in the event the FDA approves the EVER NDA and from the use, marketing and/or sale of the proposed EVER NDA Product in the U.S., including in the State of Illinois." Doc. 73, Compl. ¶ 13; *see also* ¶ 64. Although conclusory, the allegation as to financial benefit is supported by the EVER NDA. Financial benefit can be reasonably inferred from SHC's and Ruyuan's involvement in the EVER NDA's preparation. Moreover, Dr. Mei and Lin do not deny that SHC and Ruyuan will financially benefit in the event the FDA approves the EVER NDA. Their declarations are in the present tense. For example, Dr. Mei merely states that SHC currently "does not offer to sell or sell any products" in Illinois or "has not derived any revenue from any sale of" "trabectedin API, intermediate and/or starting material for the manufacture of trabectedin, or the proposed EVER NDA Product in the State of Illinois." Doc. 87-1, Mei Dec. ¶¶ 5-6. Likewise, Lin states that Ruyuan *currently* "does not offer to sell or sell any products" in Illinois and that Ruyuan "has not derived any revenue from any sale of" "trabectedin API, intermediate and/or starting material for the manufacture of trabectedin, or the proposed EVER NDA Product in the State of Illinois." Doc. 97-1, Lin Dec. ¶¶ 5-6. These statements do not address whether in the future, in the event of

FDA approval, SHC and Ruyuan will offer to sell, sell, or derive revenue from the sale of the EVER NDA Product. Accordingly, the Court accepts the reasonable inference that SHC and Ruyuan would each benefit from the EVER NDA's approval. *AbbVie*, 2021 WL 373773, at *8 (concluding that patentee's complaint adequately alleged that defendant would financially benefit from the FDA approval where defendant would engage in the commercial manufacture and supply of a biologic drug as well as its development and registration). Moreover, this patent infringement litigation arises out of or relates to SHC's and Ruyuan's submission of the EVER NDA. *Id*. at *12 (finding manufacturer defendant's submission of application to the FDA was suit-related because the application indicated defendant's intent to market and distribute its drug in Illinois).

The Court turns next to whether the exercise of jurisdiction would be unreasonable. The reasonableness inquiry involves balancing: (1) the burden on the defendant; (2) the forum State's interest in adjudicating the dispute; (3) the plaintiff's interest in obtaining convenient and effective relief; (4) the interstate judicial system's interest in obtaining the most efficient resolution of controversies; and (5) the shared interest of the several States in furthering fundamental substantive social policies. *Apple*, 30 F.4th at 1379 (the *Burger King* factors). SHC and Ruyuan bear the burden to show a "compelling case" that jurisdiction is unreasonable. *Xilinx, Inc. v. Papst Licensing GmbH & Co. KG*, 848 F.3d 1346, 1356 (Fed. Cir. 2017).

SHC and Ruyuan make no argument that the *Burger King* factors three, four and five weigh against a finding of personal jurisdiction so they have waived any such argument. *C&N Corp. v. Gregory Kance & Illinois River Winery, Inc.*, 756 F.3d 1024, 1026 (7th Cir. 2014); *Winsett v. Washington*, 130 F.3d 269, 273 (7th Cir. 1997). In any case, by not addressing these factors, SHC and Ruyuan have not met their burden of establishing that these factors indicate that exercising jurisdiction over SHC and Ruyuan would be unreasonable. The Court's analysis will thus focus

on the arguments SHC and Ruyuan present. SHC and Ruyuan limit their arguments on the reasonableness inquiry to three issues: (1) they would be significantly burdened if they were forced to defend themselves in Chicago; (2) Illinois has no interest in this matter because they have no contact with it nor do they do business within it or with its residents so they would not reasonably anticipate being haled into this Court; and (3) Plaintiffs have failed to allege facts that demonstrate that they have sufficient minimum contacts with Illinois. These arguments are unavailing.

SHC and Ruyuan argue that they would be significantly burdened if they are forced to defend themselves in Chicago. They remind the Court that they are companies based in China and they have no offices, facilities, properties, or employees in Illinois. While adjudication in Illinois will create some burden for SHC and Ruyuan, the burden on them "is not heavy because modern transportation has 'made the defense of a lawsuit in a foreign tribunal less burdensome.'" *LG Elecs., Inc. v. The P'ships & Unincorporated Ass'ns Identified in Schedule A*, 2021 WL 5742389, *3 (N.D. Ill. Dec. 2, 2021) (quoting *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1569 (Fed. 1994)); *Chamberlain Grp, Inc. v. Techtronic Indus. Co., Ltd.*, 2017 WL 3394741, at *7 (N.D. Ill. Aug. 8, 2017) ("traveling to Illinois from Hong Kong—to the extent such travel is necessary in this patent infringement action—does burden [defendant]" "but only slightly."). Moreover, there are other considerations which outweigh the slight burden on SHC and Ruyuan. Plaintiffs argue that "[Illinois] has an interest in providing a forum to resolve" the suit against SHC and Ruyuan because that suit "involve[s] the pricing and sale of products in [Illinois] and harms to firms doing business in [Illinois]." Doc. 108 at 16-17 (citing *Acorda*, 817 F.3d at 764). SHC and Ruyuan offer no counter argument on this point. Indeed, "[t]he State of Illinois has a strong interest in preventing patent infringement within its borders and discouraging injuries within the State." *LG Elecs., Inc.*, 2021 WL 5742389, *3. Illinois "also has a substantial interest in

cooperating with other states to provide a forum for efficiently litigating plaintiff's cause of action." *Beverly Hills Fan Co.*, 21 F.3d at 1568. Balancing Illinois' significant interests against the modest burden on SHC and Ruyuan supports the exercise of specific personal jurisdiction over them in Illinois. Thus, the mere fact that SHC and Ruyuan are foreign entities does not override Illinois' interests. *Chamberlain Grp, Inc.*, 2017 WL 3394741, at *7 ("[L]ike the Chinese defendant in *Beverly*," TTI HK's "mere foreign status does not outweigh these interests.") (internal quotes and citation omitted). In addition, the Court has previously established that SHC's and Ruyuan's plans to be involved in the manufacture of the API used in the generic drug which will be marketed and sold in Illinois if the NDA is approved provides sufficient specific showing of minimum contacts with Illinois. On this record, making all reasonable inferences in Plaintiffs' favor, these activities make it reasonably foreseeable that SHC and Ruyuan would be haled into court in Illinois. On balance, SHC's and Ruyuan's arguments fail to meet their burden of establishing that this is "one of the rare situations in which sufficient minimum contacts exists but where the exercise of jurisdiction would be unreasonable." *Apple*, 30 F.4th at 1381 (internal quotes and citation omitted). Therefore, the Court concludes that its exercise of specific jurisdiction satisfies the reasonableness inquiry and does not violate due process.

For the reasons stated above, Plaintiffs have made a prima facie showing of personal jurisdiction, and litigating this case in this district does not offend traditional notions of fair play and substantial justice. SHC's and Ruyuan's motions to dismiss for lack of personal jurisdiction are denied on these grounds.

II. MCE's Motion Regarding Venue

MCE moves to dismiss under Rule 12(b)(3) for improper venue. Title 28, United States Code, Section 1400(b) is the "sole and exclusive provision controlling venue in patent

infringement actions, and . . . is not to be supplemented . . . by § 1391(c)." *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 581 U.S. 258, 266 (2017) (internal quotes and citation omitted). Under Section 1400(b), venue is proper in a patent action only "where the defendant resides, or where the defendant has committed acts of infringement *and* has a regular and established place of business." 28 U.S.C. § 1400(b) (emphasis added). "[A] domestic corporation 'resides' only in its State of incorporation for purposes of the patent venue statute." *TC Heartland*, 581 U.S. at 262. Plaintiffs bear the burden of establishing that venue is proper in this judicial district. *In re ZTE (USA) Inc.*, 890 F.3d 1008, 1013 (Fed. Cir. 2018). Although the Court must accept all well-pleaded facts as true, it need not credit mere conclusory allegations regarding venue. *Westech Aerosol Corp. v. 3M Co.*, 927 F.3d 1378, 1382 (Fed. Cir. 2019). Whether venue is appropriate in a patent infringement action is unique to patent law and thus, Federal Circuit law applies. *In re Volkswagen Grp. of America, Inc.*, 28 F.4th 1203, 1207 (Fed. Cir. 2022).

Plaintiffs do not allege that MCE, a New Jersey LLC with its principal place of business in New Jersey, "resides" in the Northern District of Illinois. Doc. 73, Compl. ¶ 9. Rather, it argues that MCE has committed acts of infringement in this District and has a regular and established place of business in this District. The "regular and established place of business" inquiry has three requirements: "(1) there must be a physical place in the district; (2) it must be a regular and established place of business; and (3) it must be the place of the defendant." *In re Cray, Inc.*, 871 F.3d 1355, 1360 (Fed. Cir. 2017). Under the second *Cray* factor, "a regular and established place of business" means "the regular, physical presence of an employee or agent of the defendant conducting the defendant's business at the alleged 'place of business.'" *In re Google LLC*, 949 F.3d 1338, 1345 (Fed. Cir. 2020). If any statutory requirement is not satisfied, venue is improper under § 1400(b). *Cray*, 871 F.3d at 1360. When considering whether the *Cray* requirements are

met, the Court bears in mind that "the Supreme Court has repeatedly cautioned against a broad reading of the patent venue statute." *In re Volkswagen*, 28 F.4th at 1208; *In re ZTE (USA) Inc.*, 890 F.3d at 1014 (Section 1400(b) "is intended to be restrictive of venue in patent cases."). Moreover, in applying Section 1400(b), it is important "not to conflate showings that may be sufficient for other purposes, *e.g.*, personal jurisdiction or the general venue statute, with the necessary showing to establish proper venue in patent cases." *Cray*, 871 F.3d at 1361.[6]

Taking the second requirement under Section 1400(b) first, the Court finds that Plaintiffs fail to satisfy its burden to show that MCE has a "regular and established place of business" in this district. According to MCE, it has no physical office or physical presence in the State of Illinois; it does not own, rent, lease, or possess any real property in Illinois; it has no place of business or location of business of any kind in the State of Illinois; and it does not employ any Illinois residents. Doc. 87-2, Gao Dec. ¶ 4. Faced with this evidence, Plaintiffs argue that MCE's "engage[ment] in the business of selling chemicals and biochemicals for the development of pharmaceutical products . . . in Illinois" demonstrates a regular and established place of business in this district. *See* Doc. 91 at 22; *see also* Doc. 91 at 16 n.5.[7] Plaintiffs also contend that MCE has a "close relationship" with Defendant Nexus—an Illinois company—"by way of an agency or

[6] As the Federal Circuit has recognized, there are strong policy reasons for not adopting a narrow reading of the venue statute for patent cases. "For example, a generic company may 'game' the system to avoid venue in certain jurisdictions." *Valeant*, 978 F.3d at 1383. "And brand name drug companies may be required to file and maintain largely identical suits in multiple districts causing an increase in time and expense to resolve the cases and result[ing] in inconsistent judgments." *Id*. (internal quotes and citation omitted). The Federal Circuit has held, however, that these policy considerations cannot veto the plain language of the statute. *Id*.

[7] Plaintiffs assert that MCE serves as a manufacturer and supplier of trabectedin in the United States generally. Doc. 91 at 16 n.5. Plaintiffs further point out that MCE serves as a supplier of trabectedin to Fisher Scientific, which sells said trabectedin in the United States. *Id*. Plaintiffs also note that academic publications from researchers in Ohio have also listed MCE as a source of trabectedin used in their experiments. *Id*. Further, Plaintiffs claim that MCE's website sells trabectedin-d3 to buyers in the United States. *Id*.

other relationship [] that allows Nexus's contacts to be imputed to" MCE based on MEC's alleged actions in concert with Nexus to prepare the EVER ANDA. Doc. 91 at 21-22.

None of these arguments win the day for Plaintiff. For one, Plaintiffs do not provide any legal authority for the proposition that selling products alone within a district amounts to an established place of business for purposes of the patent venue statute. *See Regents of Univ. of Minn. v. Gilead Sciences, Inc.*, 299 F. Sup.3d 1034, 1042 (D. Minn. Oct. 20, 2017) (finding plaintiff's emphasis on defendant's sales figures in the district was misplaced as "*Cray* emphasizes that defendants must maintain a permanent and continuous place in the district in question."). For another, the Court is not persuaded that Nexus's contacts can be imputed to MCE for venue purposes under an agency or "close relationship" theory. The Complaint does not suggest that MCE and Nexus are related or affiliated companies. Indeed, the only factual allegations specific to MCE's relationship is that it is a subsidiary of Defendant HCE and MCE and that they "operate and act in concert as an integrated, unitary business with respect to the manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in Illinois." Doc. 73, Compl. ¶¶ 9, 40. Nor does the Complaint provide any factual basis that would support that MCE had an agency relationship with Nexus for NDA preparation activities.[8] At most, the Complaint offers an allegation that MCE "operates in concert with and under the direction of H[CE], EVER [] and Nexus in [] seeking approval for the EVER NDA, supported by DMF Nos. 36724 and 36899, and the development and manufacture of the trabectedin API

[8] Agency is a "fiduciary relationship that arises when one person (a 'principal') manifests assent to another person (an 'agent') that the agent shall act on the principal's behalf and subject to the principal's control, and the agent manifests assent or otherwise consents so to act." *In re Google LLC*, 949 F.3d at 1345 (quoting Restatement (Third) of Agency § 1.01). "The essential elements of agency are (1) the principal's 'right to direct or control' the agent's actions, (2) 'the manifestation of consent by [the principal] to [the agent] that the [agent] shall act on his behalf,' and (3) the 'consent by the [agent] to act.'" *Id*. (quoting *Meyer v. Holley*, 537 U.S. 280, 286 (2003)).

manufactured for the proposed EVER NDA Product." *Id.* ¶ 9.[9] But that allegation is conclusory in nature and lacks facts to support that those entities controlled MCE's work with respect to the preparation of the EVER NDA. *Commodity Futures Trading Commission v. Skudder*, 2022 WL 17752392, at *5 (N.D. Ill. (N.D. Ill. Dec. 19, 2022) (after *Iqbal*, "a conclusory allegation of an agency relationship isn't enough."); *see also Warciak v. Subway Restaurants, Inc.*, 949 F.3d 354, 357 (7th Cir. 2020). Accordingly, Plaintiffs have not plausibly alleged an agency relationship between MCE and Nexus with respect to the preparation of the EVER NDA.

Alternatively, Plaintiffs argue that they should be allowed discovery on the issue of whether and to what extent MCE has a presence in this district, including under an agency theory or "other relationship" that would allow Nexus' contacts to be imputed to MCE. "The Federal Circuit does not appear to have addressed whether Federal Circuit law or regional circuit law applies when considering a request for venue discovery for purposes of § 1400(b)." *Loyal-T Sys. LLC v. Am. Express Co.*, 2024 WL 4381835, at *9 n. 6 (D. N.J. Oct. 3, 2024); *Delta Elecs., Inc. v. Vicor Corp.*, 724 F. Supp. 3d 645, 655 (W.D. Tex. 2024). District courts have applied regional circuit law to such venue discovery requests. *Loyal-T Sys. LLC*, 2024 WL 4381835, at *9 n. 6 (citing cases); *Delta Elecs., Inc.*, 724 F. Supp.3d at 656-57. This Court will do the same.

In the Seventh Circuit, district courts have discretion to authorize limited discovery into venue issues, but "a court is not obligated to do so when the plaintiff fails to make even a prima facie case that [proper venue] exits." *Sanderson v. Spectrum Labs, Inc.*, 248 F.3d 1159, *3 (7th Cir. 2000). Plaintiffs have not done so here, and they are not entitled to venue discovery. In the Complaint, Plaintiffs make general, conclusory allegations that MCE acted in concert with Nexus

[9] MCE denies coordination with any of Defendants in this lawsuit in seeking approval for the EVER NDA and in the development and manufacture of the trabectedin API for the EVER NDA Product. *See* Doc. 87-2, Gao Dec. ¶ 7.

to prepare the EVER NDA and MCE "is engaged in the business of selling chemicals and biochemicals for the development of pharmaceutical products … in Illinois," but they fail to allege any facts showing that MCE's actions were subject to Nexus' control. Doc. 73, Compl. ¶¶ 9, 37. Plaintiffs' conclusory assertions do not convince the Court that additional discovery would alter the Court's conclusion. Moreover, because Plaintiffs have not cited any authority showing that the mere presence of coordination or a "close relationship" between MCE and Nexus on the NDA is sufficient to establish that MCE has a regular and established place of business in this district, any such discovery would be futile. *Unity Opto Tech. Co., Ltd. v. Lowe's Home Centers, LLC*, 2018 WL 2087250, at *3 (W.D. Wis. May 4, 2018) (holding that under Section 1400(b), "there is no authority for the view that venue is proper as to one corporation simply because that corporation 'works closely' with another corporation that may be sued in that district."). By failing to plausibly allege Nexus' control over the actions of MCE for NDA preparation work, Plaintiffs failed to make a prima facie case that venue was proper. Under these circumstances, the Court declines to defer ruling on MCE's motion in order to permit limited venue discovery.

Having concluded that Plaintiffs failed to meet their burden in establishing that MCE has a regular and established place of business in this district, the Court need not consider the issue of whether MCE committed an act of infringement in this district under the first prong of § 1400(b). MCE requests dismissal with prejudice if the Court finds venue improper. That request is denied because any dismissal would be without prejudice. *Peters v. Sloan*, 762 F. App'x 344, 346 (7th Cir. 2019) ("[d]ismissals for lack of [] venue ordinarily are without prejudice."); *Johnson v. W. & S. Life Ins. Co.*, 598 F. App'x 454, 456 (7th Cir. 2015) ("[A] dismissal for improper venue is without prejudice because it is not an adjudication on the merits."). In the alternative to dismissal,

Plaintiffs request that the Court transfer this case to the District of New Jersey (the district in which MCE resides).

The Court has broad discretion to either dismiss the case, or if it is in the interest of justice, transfer it to a venue in which it could have been brought. 28 U.S.C. § 1406(a); *Cote v. Wadel*, 796 F.2d 981, 985 (7th Cir. 1986). "Generally, courts prefer transferring a case to a jurisdiction where venue is proper as opposed to dismissing it. Transfer avoids the 'time-consuming and justice-defeating technicalities' required to refile a case in a proper venue." *Hangxiao Che v. Daimler Trucks N. Am., LLC*, 2021 WL 3129418, at *4 (S.D. Ill. July 23, 2021) (quoting *Goldlawr, Inc. v. Heiman*, 369 U.S. 463, 467 (1962)); *see also MB Fin. Bank, N.A. v. Walker*, 741 F. Supp.2d 912, 919 (N.D. Ill. 2010) ("the presumption generally runs in favor of transfer."); *Van Gelder v. Taylor*, 621 F. Supp. 613, 621–22 (N.D. Ill. 1985) ("Normally, if venue is not proper in the district court where the action is initiated, transfer to a proper district or division is preferred over dismissal.").

MCE does not respond to Plaintiffs' argument regarding transfer in its reply brief, nor does MCE suggest an alternative forum. The Court finds that the interests of justice would be best served by transfer of the case against MCE to the District of New Jersey, where both parties concede venue would have been proper. Dismissing a case that can be pursued elsewhere is also inefficient. Given the need for swift resolution of Hatch-Waxman litigation, transfer is the better alternative. Transfer, rather than dismissal, will eliminate the delay and expense involved in re-filing this action as to MCE and re-serving MCE. Based on these circumstances, transfer of the case as to MCE to the District of New Jersey is appropriate under 28 U.S.C. § 1406(a). Accordingly, the Court denies MCE's motion to dismiss under Rule 12(b)(3) for improper venue,

instead transferring the case against it to the District of New Jersey.[10] The Court severs MCE from this suit and directs the Clerk to transfer the case as to MCE to the United States District Court for the District of New Jersey.

III. Motions Under Rule 12(b)(1) to Dismiss Count III

Defendants next argue that Count III asserting future infringement of the '051 Patent under 35 U.S.C. § 271(g) should be dismissed because there is no ripe controversy. Section 271(g) prohibits unauthorized importation, use, selling or offering to sell "within the United States a product which is made by a process patented in the United States . . . ." 35 U.S.C. § 271(g). The trabectedin that will be used in EVER's NDA Product is made outside the United States by SHC and Ruyuan. In their motions to dismiss, Defendants assert that because EVER's NDA Product is not yet FDA-approved, it cannot yet be imported for use or sale. Defendants also argue that they cannot have taken steps to actively market a trabectedin product because FDA approval is not imminent.[11] Thus, according to Defendants, any future infringement claim is not ripe because Plaintiffs do not allege that FDA approval and importation are imminent. In response, Plaintiffs argue that they have alleged an actual controversy because upon FDA approval, Defendants will import, offer to sell, sell, or use in the United States the EVER NDA Product, which will infringe

[10] As a result, the Court declines to reach the merits MCE's motion to dismiss under Rule 12(b)(2) for lack of personal jurisdiction, Rule 12(b)(1) for lack of subject matter jurisdiction, and 12(b)(6) for failure to state a claim.

[11] Defendants also argue that any trabectedin API made to date relating to EVER's proposed generic product was made and studied for the purpose of obtaining FDA approval and is protected by the "safe harbor" provision of the Hatch-Waxman Act. *See* 35 U.S.C. § 271(e)(1). Plaintiffs do not dispute that Defendants' activities to date have been related to seeking FDA approval. *See Glaxo, Inc. v. Novopharm, Ltd.,* 110 F.3d 1562, 1568 (Fed. Cir. 1997) ("While performing development work and seeking [ANDA] approval, a generic drug manufacturer is free from liability for patent infringement based solely upon acts necessary to prepare the ANDA.") (citing 35 U.S.C. § 271(e)(1)). Rather, Plaintiffs emphasize that their declaratory judgment claim in Count III "targets *future* acts that will occur *after* FDA approval." Doc. 92 at 12.

under § 271(g) as that product will contain trabectedin made by a process patented by the '051 Patent.

Section 271(e)(2) provides federal courts with jurisdiction to decide infringement claims directed to drugs or to methods of using drugs, but it does not provide jurisdiction to consider infringement claims directed to methods of making drugs. *See* 35 U.S.C. § 271(e)(2) (stating "[i]t shall be an act of infringement to submit" an application to the FDA "for a drug claimed in a patent or the use of which is claimed in a patent."); *Sandoz Inc. v. Amgen Inc.*, 773 F.3d 1274, 1281 (Fed. Cir. 2014) ("In the Hatch–Waxman Act, Congress did provide for certain early adjudications of patent issues that would be presented by future market-entry activity in the FDA setting. It created an 'artificial' act of infringement to allow suit by a patent holder, 35 U.S.C. § 271(e)(2)(A)."). As a result, Plaintiffs' claim that Defendants will infringe the '051 Patent under Section 271(g) is necessarily based on the Declaratory Judgment Act. The Declaratory Judgment Act provides that "[i]n a case of actual controversy . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a).

In *MedImmune,* the Supreme Court held that a party seeking to base jurisdiction on the Declaratory Judgment Act bears the burden of proving that the facts alleged, "under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (internal quotes and citation omitted). The Supreme Court has required that the dispute be "definite and concrete, touching the legal relations of parties having adverse legal interests; and that it be real and substantial and admi[t] of specific relief through a decree of a conclusive character, as

distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Id*. (internal quotes and citation omitted).

Applying the *MedImmune* standard, the Court finds that there is an inadequate basis for declaratory judgment jurisdiction over Count III. Considering the totality of the circumstances, Plaintiffs have not pled a substantial and real controversy between the parties with the requisite immediacy. Count III contains conclusory references to immediacy, but does not set forth factual allegations to support these conclusions. For example, Count III alleges that "[a] definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Defendants regarding infringement of the '051 Patent." Doc. 73 at ¶ 114. This language merely recites the legal standard without offering supporting facts. Similarly with respect to Count III, Plaintiffs allege that "Defendants have made and will continue to make substantial and meaningful preparations to import into the U.S." API made by the patented process. *Id*. at ¶ 115. However, Plaintiffs do not provide any facts regarding such preparations that are imminent. Without additional specifics, these unsupported, conclusory allegations are insufficient to establish an actual controversy exists and thus subject matter jurisdiction. *Ashcroft v. Iqbal,* 556 U.S. 662, 678, 681 (2009); *Emerson v. Dart*, 109 F.4th 936, 941(7th Cir. 2024) (when evaluating the complaint, "allegations in the form of legal conclusions" must be disregarded); *Silha v. ACT, Inc.*, 807 F.3d 169, 174 (7th Cir. 2015) (in evaluating facial challenge to subject matter jurisdiction under Rule 12(b)(1), the Court applies the *Twombly-Iqbal* "plausibility" standard).

Disregarding these legal conclusions, Count III of the Complaint alleges that: Defendants will engage in the commercial manufacture, use and/or sale of the EVER NDA Product if approved by the FDA; Defendants' actions, including but not limited to, the filing of EVER NDA with a Paragraph IV certification and Defendants' systematic attempts to meet the applicable regulatory

requirements for approval of the EVER NDA indicate a refusal to change their course of action; and Defendants' importation, use, sale, and/or offer for sale of the EVER NDA Product prior to expiration of the '051 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '051 Patent under 35 U.S.C. § 271(g). Doc. 73 at ¶¶ 116-118. Plaintiffs seek a declaration that such future conduct after FDA approval, but before the expiration of the '051 Patent, will infringe the claims of the '051 Patent under 35 U.S.C. § 271(g). Plaintiffs argue that EVER's NDA filing coupled with Defendants' failure to state that FDA approval or their future product is speculative constitute sufficient evidence to meet the immediacy requirement.

The Court disagrees and finds these allegations insufficient to state an actual controversy as required by 28 U.S.C. § 2201. Plaintiffs filed this action in August 2024 to prevent future infringement. The filing of the § 271(e)(2) claim triggered the automatic 30-month stay of FDA approval of EVER's NDA. Defendants cannot manufacture, import, offer to sell, sell, or use the EVER NDA Product in the United States without FDA approval. The stay will remain in place until the earlier of the expiration of the stay or the conclusion of this case. The 30-month stay expires in February 2027 and trial in this action is set for October 5, 2026. At present, there is no sufficient immediacy to the controversy Plaintiffs allege in Count III. A controversy will only materialize if and when FDA approval is known to be imminent and Defendants intend to launch their generic drug. *See Scilex Pharms. Inc. v. Aveva Drug Delivery Systems, Inc.*, 2022 WL 22824885, at *6 (S.D. Fla. Dec. 14, 2022) (finding no sufficient immediacy to the controversy because "the alleged future infringement depends on two future events: FDA approval of the ANDA and the decision to market the ANDA Product."); *Reckitt Benckiser Pharms., Inc. v. Biodelivery Sciences Intern., Inc.*, 2014 WL 2119822, at *2 (E.D.N.C. May 21, 2014) (where

accused infringer filed a NDA and the FDA has not yet approved the application, granting motion to dismiss patentee's declaratory judgment infringement claim for lack of an actual controversy because "any actual future alleged infringement of plaintiffs' claim for future infringement depends on two contingent future events: "FDA approval of [defendant's] []NDA, and [defendant's] decision to market [Bunavail] pursuant to that []NDA. At least until the []NDA is approved . . . the controversy is not sufficiently immediate."); *Eisai Co. v. Mut. Pharm. Co.*, 2007 WL 4556958, at *18 (D. N.J. Dec. 20, 2007) (same).[12] Moreover, the fact that Defendants have failed to state that they do not plan to enter the market is insufficient to meet Plaintiffs' burden to claim plausibly that FDA approval and launch are imminent. *See Abbott Laboratories v. Zenith Laboratories, Inc.*, 934 F. Supp. 925, 938 (N.D. Ill. 1995) (finding no actual controversy because "[t]he FDA has not given Defendant approval to market a generic form of HYTRIN and the fact that Defendant has not indicated that it does not plan to enter the market is not sufficient to show that Defendant intends to enter the market."). Therefore, immediacy is lacking because there is no indication that either FDA approval or importation, use, sale, and/or offer for sale of the EVER NDA Product is imminent.

Plaintiffs rely primarily on *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997) to argue that their declaratory judgment claim under Section 271(g) is ripe. In *Glaxo*, the defendant submitted an ANDA seeking approval to make and sell a generic version of the patentee's drug prior to patent expiration. The patentee brought an "artificial" infringement claim under Section 271(e)(2) and a declaratory judgment claim based on a "method of making" patent,

[12] *See also Valent Intern. Bermuda v. Spear Pharms., Inc.*, 2012 WL 4513046, at *5 (M.D. Fla. Sept. 30, 2012); *In re Rosuvastatin Calcium Patent Litig.*, 2008 WL 5046424, at *12-13 (D. Del. Nov. 24, 2008); *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, 2006 WL 2375035, at *3 (D. Del. Aug. 16, 2006).

which the patentee could not assert under Section 271(e)(2). *Id*. at 1564. The Federal Circuit upheld the district court's decision to hear the declaratory judgment for a method of manufacturing patent based on an ANDA because the plaintiffs had alleged sufficient facts to create an actual case or controversy. *Id*. at 1571. Those facts included "imminent FDA approval and actual threats of future infringement." *Id*. *Glaxo* is distinguishable from the present case. In *Glaxo*, the complaint was based in part on a letter in which the alleged infringer indicated that "it had submitted an ANDA accompanied by data sufficient to make FDA approval imminent." *Id*. Here, in contrast, Plaintiffs do not allege imminent FDA approval of EVER's NDA Product. The Complaint also does not allege facts which would allow the Court to plausibly infer the requisite immediacy. Because Plaintiffs have not alleged sufficient facts from which the Court can conclude that FDA approval is imminent or even certain, the Court concludes that no controversy of sufficient immediacy and reality exists to support declaratory judgment jurisdiction as to Count III. As such, the Court grants Defendants' motion to dismiss Count III of the Complaint without prejudice.

IV. Motions Under Rule 12(b)(6)

The Court now turns to the three motions to dismiss for failure to state a claim under Rule 12(b)(6). Federal Rule of Civil Procedure 12(b)(6) provides that a viable complaint need only contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). A complaint must "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal quotes and citation omitted). The Supreme Court has explained that to survive a motion to dismiss under Rule 12(b)(6), a complaint must provide "only enough facts to state a claim to relief that is plausible on its face." *Id*. at 570. A claim is plausible where the plaintiff "pleads factual content

that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A "complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations," but there "must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555; *Bilek*, 8 F.4th at 586 ("We have considered that *Twombly* and *Iqbal* require the plaintiff to provid[e] some specific facts to support the legal claims asserted in the complaint.") (internal quotes and citation omitted). The Court assumes the truth of the allegations in the complaint and construes the complaint and all reasonable inferences in plaintiffs' favor. *Burke v. Boeing Co.*, 42 F.4th 716, 723 (7th Cir. 2022).

First, the Court considers Plaintiffs' claims of direct, induced, and contributory infringement. Plaintiffs bring two counts for patent infringement of the '557 patent, Count I for infringement under 35 U.S.C. § 271(e)(2)(A) and Count II for infringement of under 35 U.S.C. § 271(a), (b), and/or (c). Plaintiffs advance both counts against all Defendants. Defendants SHC and Ruyuan seek dismissal of Count I, arguing that they cannot infringe the '557 Patent under 35 U.S.C. § 271(e)(2)(A) because neither SHC nor Ruyuan is a submitter of the EVER NDA. The Court has already dealt with this argument, finding that the record adequately supports a prima facie case that SHC and Ruyuan are submitters of the EVER NDA because they will each be involved in manufacturing the trabectedin API that will be used in the NDA Product if the NDA is approved. *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1378 n.5 (Fed. Cir. 2012) (holding that it was not error for the district court to consider statements in defendants' ANDA filings when ruling on a motion to dismiss).

Further, Defendants SHC and Ruyuan assert that the Complaint fails to state a claim for indirect infringement (induced and contributory infringement) under 35 U.S.C. § 271(e)(2) as to the '557 Patent (Count I) against them. "Whoever actively induces infringement of a patent shall

be liable as an infringer." 35 U.S.C. § 271(b). To state a claim for induced infringement, a plaintiff must plausibly plead that "the alleged inducer [1] knew of the patent, [2] knowingly induced the infringing acts, and [3] possessed a specific intent to encourage another's infringement of the patent." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1328 (Fed. Cir. 2009); *Allergan, Inc. v. Alcon Labs, Inc.*, 324 F.3d 1332, 1336 (Fed. Cir. 2002) (Schall and Clevenger, J., concurring) ("In order to prevail on a claim of induced infringement under section 271(e)(2), patent holder must establish the traditional elements of a claim of induced infringement."). Contributory infringement is governed by 35 U.S.C. § 271(c). To state a claim for contributory infringement, a complaint must adequately allege: "(1) the defendant had knowledge of the patent in suit; (2) the defendant had knowledge of patent infringement; and (3) the accused product is not a staple article or commodity of commerce suitable for a substantial non-infringing use." *AlexSam, Inc. v. Aetna, Inc.*, 119 F.4th 27, 47 (Fed. Cir. 2024) (internal quotes and citation omitted). Further, the product must constitute "a material part of the invention." *Id.* (internal quotes and citation omitted). The Complaint has only one conclusory sentence about these claims. Doc. 73 at ¶100. In their response memo, Plaintiffs devote one sentence to its indirect infringement theories regarding the '557 Patent, stating only that "[t]he factual allegations supporting direct infringement also support indirect infringement." Doc. 91 at 20. Plaintiffs cite no case law and do not explain how the allegations in the Complaint plausibly suggest that the indirect infringement elements might be met. *See M.G. Skinner & Assocs. Ins. Agency, Inc. v. Norman-Spencer Agency, Inc.*, 845 F.3d 313, 321 (7th Cir. 2017) ("Perfunctory and undeveloped arguments are waived, as are arguments unsupported by legal authority."); *Schaefer v. Universal Scaffolding & Equip., LLC*, 839 F.3d 599, 607 (7th Cir. 2016) (same). Without more, the Court cannot find that Plaintiffs have stated

plausible claims of indirect infringement as to the '557 Patent. Accordingly, Plaintiffs claims of induced and contributory infringement of the '557 Patent are dismissed.

SHC and Ruyuan also seek dismissal of Count II for declaratory judgment of infringement of the '557 Patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (c). SHC and Ruyuan argue that Plaintiffs have not alleged a controversy of sufficient immediacy and reality that exists between Plaintiffs and Defendants regarding future, potential infringement of the '557 Patent under section 271(a), (b), and/or (c). The Court agrees. "While not all courts are in agreement as to this issue, courts routinely dismiss § 271(a), (b), and (c) claims for future infringement because there is simply no sufficient immediacy to the controversy and the claims appear inconsistent with Congressional intent, as plaintiffs have an express statutory remedy designed to provide full relief" in 35 U.S.C. § 271(e)(2). *Scilex Pharms. Inc.*, 2022 WL 22824885, at *6 (citing cases). For similar reasons raised under the discussion of Defendants' challenge under Rule 12(b)(1) as to the '051 Patent in Count III, the Court finds that there is not sufficient immediacy as to the alleged future infringement of the '557 patent under section 271(a), (b), and/or (c) in Count II. Therefore, the declaratory judgment claim in Count II is dismissed without prejudice.

The Court next considers whether any of Defendants' asserted defenses—prosecution history and disclosure-dedication—bar Plaintiffs' claims of infringement under the doctrine of equivalents as to Count I.[13] Plaintiffs allege infringement of the '557 Patent under the doctrine of equivalents, specifically that the EVER NDA Product's amino acid Larginine is equivalent to a "disaccharide selected from sucrose, lactose and a combination thereof." Doc. 73, Compl. ¶¶ 92-94, 98-103, 109-10. Defendants argue that Count I asserting infringement of the '557 Patent

[13] "Under the doctrine of equivalents, even if an accused product does not satisfy every element of a patent claim literally, it may nevertheless be found to infringe if it includes the equivalent of the missing claim element(s)." *Lecat's Ventriloscope v. MT Tool & Mfg.*, 2018 WL 3651592, at *4 (N.D. Ill. Aug. 1, 2018).

should be dismissed under the theory of prosecution history estoppel. "There are certain limitations [] on a patentee's ability to obtain an infringement verdict under the doctrine of equivalents. One such limitation is prosecution history estoppel." *Bio-Rad Labs., Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1363 (Fed. Cir. 2020). "Prosecution history estoppel applies as part of an infringement analysis to prevent a patentee from using the doctrine of equivalents to recapture subject matter surrendered from the literal scope of a claim during prosecution." *Amgen Inc. v. Coherus BioSciences Inc.*, 931 F.3d 1154, 1159 (Fed. Cir. 2019) (internal quotes and citation omitted). Prosecution history estoppel can occur "either (1) by making a narrowing amendment to the claim ('amendment-based estoppel') or (2) by surrendering claim scope through argument to the patent examiner ('argument-based estoppel')." *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1363 (Fed. Cir. 2006). Whether prosecution history estoppel applies is a question of law. *Amgen*, 931 F.3d at 1159.

Defendants argue that Plaintiffs are precluded from asserting infringement under the doctrine of equivalents based on: (1) amendment-based estoppel; (2) argument-based estoppel; and (3) the disclosure-dedication rule. The Court addresses each argument in turn and finds that based on the record before it, prosecution history estoppel and the disclosure-dedication rule are not amenable to resolution at this litigation's early stage.

First, Defendants invoke amendment-based estoppel. Amendment-based "[e]stoppel arises when an amendment is made to secure the patent and the amendment narrows the patent's scope" and that amendment was made for a "substantial reason related to patentability." *Festo Corp. v. Skoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 735-36 (2002). "A patentee's decision to narrow his claims through amendment may be presumed to be a general disclaimer of the territory between the original claim and the amended claim." *Id.* at 740. Defendants assert that during the

prosecution of the '557 Patent, Plaintiffs amended the originally filed claims to narrow "disaccharide" generally to two specific disaccharides—sucrose and/or lactose—to overcome prior art. Doc. 85 at 16. As a result, Defendants contend this narrowing amendment prevents the amino acid L-arginine from being equivalent to a "disaccharide selected from sucrose, lactose and a combination thereof." *Id*. at 15-16. Plaintiffs respond that the amendment did not presumptively surrender L-Arginine as an equivalent because L-arginine is not a disaccharide. Doc. 92 at 18 (citing *Pac. Coast Marine Windshields Ltd. v. Malibu Boats, LLC*, 739 F.3d 694, 704-05 (Fed. Cir. 2014)).

Defendants' argument appears premature at the motion to dismiss stage of the proceedings. Even if the *Festo* presumption of estoppel applies here (as Defendants argue), the patent holder can rebut the presumption that the doctrine of equivalents will not apply. To do so, "[t]he patentee must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Festo*, 535 U.S. at 741. A patentee may demonstrate this by showing: "(1) the rationale underlying the amendment bears no more than a tangential relation to the equivalent in question; (2) the equivalent was unforeseeable at the time of the application; or (3) there was some other reason suggesting that the patentee could not reasonably be expected to have described the equivalent." *Bio-Rad Labs.*, *Inc.*, 967 F.3d at 1364 (citing *Festo*, 535 U.S. at 740-41). Thus, "[w]henever the doctrine is evoked, a close examination must be made as to, not only what was surrendered, but also the reason for such a surrender." *Hormone Research Foundation, Inc. v. Genentech, Inc.,* 904 F.2d 1558, 1564 (Fed. Cir. 1990). As an example here, Plaintiffs argue that given the prosecution history's focus on disacchardies, use of L-arginine bears only a peripheral relationship to the amendment, which shows tangentiality. Doc. 92 at 19 n.10.

Defendants do not address or even acknowledge these exceptions to prosecution history estoppel. This is not surprising as "the scope of estoppel depends on factual questions regarding the prosecution history, which may preclude a disposition of the issue not only on a motion to dismiss, but on summary judgment." *Kyowa Hakka Bio, Co. v. Ajinomoto Co.*, 2018 WL 834583, at *6 (D. Del. Feb. 12, 2018) (citing *Hormone Research Found.*, 904 F.2d at 1564). Given that the underlying factual issues implicated benefit from consideration of expert testimony and other extrinsic evidence, dismissal is inappropriate. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1369 (Fed. Cir. 2003) ("[U]nforeseeability depends on underlying factual issues relating to, for example, the state of the art and the understanding of a hypothetical person of ordinary skill in the art at the time of the amendment. Therefore, in determining whether an alleged equivalent would have been unforeseeable, a district court may hear expert testimony and consider other extrinsic evidence relating to the relevant factual inquiries."); *id*. at 1370 (evaluation of tangentiality may include "testimony from those skilled in the art as to the interpretation of [the intrinsic] record"); *id*. (evaluation of some other reason may also allow consideration of "evidence outside the prosecution history record"). Without the benefit of a more developed record, the Court declines to decide whether amendment-based estoppel bars Plaintiffs from relying on the doctrine of equivalents. *See*, *e.g.*, *Smithkline Beecham Corp. v. Excel Pharms., Inc.*, 356 F.3d 1357, 1364-65 (Fed. Cir. 2004) (vacating summary judgment of no infringement because a material issue of fact existed as to foreseeability); *Par Pharm., Inc. v. Baxter Healthcare Corp.*, 2024 WL 1069941, at *3-4 (D. Del. Mar. 12, 2024) (denying judgment on the pleadings based on questions regarding tangentiality that would benefit from consideration of "testimony from a person of ordinary skill in the art"); *Pfizer Inc. v. Sinotherapeutics Inc.*, 2022 WL 17989946, at *3-4 (D. Del. Dec. 29, 2022) (declining to decide on judgment on the pleadings

motion "whether amendment-based prosecution history estoppel applies and, if so, the extent of any such estoppel. Those questions may be resolved, if appropriate, at a later stage of the litigation, after the development of a full evidentiary record.").

Second, Defendants invoke argument-based estoppel. However, "[t]o invoke argument-based estoppel, the prosecution history must evince a clear and unmistakable surrender of subject matter." *Amgen*, 931 F.3d at 1159 (internal quotes and citation omitted). The court will not "presume a patentee's arguments to surrender an entire field of equivalents through simple arguments and explanations to the patent examiner." *Conoco, Inc*, 460 F.3d at 1364. "The relevant inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter." *Id*. (internal quotes and citation omitted).

In arguing that argument-based estoppel should apply, Defendants first rely on two statements by Plaintiffs about advantages of disaccharides: (1) "Applicants have discovered numerous advantages (stability purity, etc.) of formulating [trabectedin] with a disaccharide, specifically sucrose, as described in the present application." Doc. 85-4 at 11, 7/20/08 Response and (2) "Applicants have surprisingly found that a composition of [trabectedin] and a disaccharide has an advantage, which would not have been apparent to the skilled person in view of the art cited by the examiner." Doc. 85-5 at 20, 2/22/10 Response. Based on that language, Defendants assert that Plaintiffs "secure[d] the patent by arguing that the claims only cover two ingredients, and expressly exclude[d] other ingredients" and therefore "cannot later assert the contrary." Doc. 85 at 17. Defendants also point to a statement distinguishing the monosaccharide mannitol from the disaccharide sucrose, stating that "[a]s clearly disclosed in Applicants' specification, mannitol (a monosaccharide) and disaccharide (specifically, sucrose) are not equivalent excipients when

applied to an ecteinascidin compound formulation (specifically, ET-743)." Doc. 85-4 at 12-13, 7/20/08 Response (emphasis in original).

In response, Plaintiffs argue that the three statements in Defendants' motions are insufficient to establish a clear and unmistakable surrender of subject matter. Plaintiffs argue that the first two statements, which contain no words of exclusion, do not reflect a clear and unmistakable surrender of anything at all and certainly, the statements do not clearly and unmistakably surrender L-arginine. Plaintiffs point out that these statements do not mention L-arginine or any amino acid. Doc. 92 at 20 (citing *Baseball Quick, LLC v. MLB Advanced Media L.P.*, 2014 WL 6850965, at *9 (S.D.N.Y. Dec. 4, 2014), *aff'd,* 623 F. App'x 1012 (Fed. Cir. 2015)). ("Generally, courts will only find argument-based estoppel appropriate when the patentee has *explicitly disavowed* a *specific feature* in the prior art; additional statements meant to further distinguish the claimed invention from prior art do not constitute clear and unmistakable surrender."). As to the third statement, Plaintiffs argue that it cannot show disclaimer of L-arginine because L-arginine is neither a mannitol nor a monosaccharide.

The Court declines to find on the record before it that argument-based estoppel bars L-arginine from being equivalent to the claimed disaccharides as a matter of law. It is true that the applicability of argument-based prosecution history estoppel may sometimes be decided on a motion to dismiss because it is a question of law. *See Amgen*, 931 F.3d at 1159. But the relevant case law suggests that this analysis depends on context, viewing the prosecution as a whole, not just the specific language used in the prosecution history. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1252 (Fed. Cir. 2000) ("In determining whether there has been a clear and unmistakable surrender of subject matter, the prosecution history must be examined as a whole."); *see also Galderma Labs., L.P. v. Amneal Pharms. LLC*, 806 F. App'x 1007, 1010 (Fed. Cir. 2020)

("Statements by the patent owner are not considered in a vacuum; rather, the skilled artisan would look at the record as a whole in assessing claim scope."); *CAE Screenplates Inc. v. Heinrich Fiedler GmbH & Co. KG,* 224 F.3d 1308, 1319 (Fed. Cir. 2000) ("It is the totality of the prosecution history which defines and establishes the metes and bounds of the patent grant."); *Amgen Inc. v. Coherus Biosciences Inc.*, 2018 WL 1517689, at *4 (D. Del. Mar. 26, 2018), *aff'd*, 931 F.3d 1154 (Fed. Cir. 2019) (on motion to dismiss, district court found it had "sufficient context" to "make a decision of law that prosecution history estoppel applie[d]."). Significantly, the briefing here does not sufficiently address the context from the prosecution history relevant to this issue. Accordingly, the Court has no arguments about the context in which Plaintiffs made the statements at issue from which to determine which inferences may properly be drawn from the prosecution history, nor to decide as a matter of law that prosecution history estoppel applies. Moreover, testimony about the applicability of prosecution history estoppel may be useful to the Court. *See Bayer*, 212 F.3d at 1254 (although "testimony as to what a reasonable competitor would conclude from the prosecution history cannot create a genuine issue of material fact so as to bar summary judgment," [s]uch testimony is [] a tool, which the judge can use at his or her discretion, to aid in the legal determination of prosecution history estoppel."). In sum, the Court finds the record and the briefing insufficient to rule on this issue, so the Court will not grant Defendants' motion on this point. The Court will evaluate the parties' dispute on this issue with benefit of a more developed record and fuller briefing at an appropriate stage of the litigation.[14]

[14] In one sentence, Defendants also contend that Plaintiffs' doctrine of equivalents theory vitiates the disaccharide limitation. Doc. 85 at 18. It is not clear if this is a new legal argument or merely reframes its argument-based estoppel argument discussed above. If this is a new argument, the Court finds the one-sentence argument waived. The Seventh Circuit has repeatedly stated that perfunctory and undeveloped arguments are waived. *See M.G. Skinner & Assocs. Ins. Agency, Inc. v. Norman-Spencer Agency, Inc.*, 845 F.3d 313, 321 (7th Cir. 2017) ("Perfunctory and undeveloped arguments are waived, as are arguments unsupported by legal authority."); *Schaefer v. Universal Scaffolding & Equip., LLC*, 839 F.3d 599, 607 (7th Cir. 2016) (same).

Finally, the Court turns to Defendants' argument that the disclosure-dedication rule prohibits Plaintiffs from asserting infringement under the doctrine of equivalents.[15] "[W]hen a patent drafter discloses but declines to claim subject matter . . . this action dedicates that unclaimed subject matter to the public." *Johnson & Johnston Assocs. v. R.E. Servs. Co., Inc.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002). The inquiry requires a showing that "one of ordinary skill in the art can understand the unclaimed disclosed teaching upon reading the written description." *PSC Computer Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004). "The disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed." *Id.* Only subject matter that is "disclosed, but not claimed" in a patent will be deemed "dedicated to the public" and ineligible for recapture under the doctrine of equivalents. *Johnson & Johnston Assocs.*, 285 F.3d at 1054. Application of the disclosure-dedication rule is a question of law. *Eagle Pharms. Inc. v. Slayback Pharma LLC*, 958 F.3d 1171, 1177 (Fed. Cir. 2020).

Quoting the following language from the '557 Patent specification, Defendants argue L-arginine is disclosed, but not claimed, in the '557 Patent: "[t]he stability of the formulation comprising disaccharides is also improved in comparison with other formulations containing other bulking agents such as dextran and povidone." Doc. 85 at 18. Plaintiffs contend the disclosure-dedication doctrine does not bar their infringement allegations under the doctrine of equivalents because the '557 Patent specification contains no explicit disclosure of an amino acid, let alone L-arginine. More specifically, Plaintiffs argue that dextran and povidone are not L-arginine. In reply, Defendants argue that the category of "conventional bulking agents" includes L-arginine.

[15] The Federal Circuit refers to the rule as the "disclosure-dedication rule" and the "dedication-disclosure rule." *ViiV Healthcare Co. v. Gilead Sciences, Inc.*, 437 F. Supp.3d 395, 399 n.1 (Fed. 5, 2020).

Although the '557 Patent application discloses dextran and povidone as known bulking agents, it does not explicitly disclose L-arginine. On this record, therefore, the Court finds that it is premature to determine whether a person of ordinary skill in the art would recognize L-arginine as a disclosed alternative to disaccharides and trigger the disclosure-dedication rule. *See Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1378-79 (Fed. Cir. 2005) ("[b]efore unclaimed subject matter is deemed to have been dedicated to the public, that unclaimed subject matter must have been identified by the patentee as an alternative to a claim limitation."). Moreover, although not always the case, expert testimony may be "required for a district court to determine how a skilled artisan would understand a patent's disclosure and claimed invention." *Eagle Pharms. Inc.*, 958 F.3d at 1177 (in ruling on motion for judgment of non-infringement on the pleadings, district court decided it had "sufficient context to decide question of law, i.e., that the disclosure-dedication doctrine applies to bar Eagle's claims for infringement under the doctrine of equivalents."). Indeed, the cases cited by Defendants applying the disclosure-dedication rule were decided on a complete record following discovery. *See PSC Computer Prods., Inc.,* 355 F.3d at 1360-61 (decided on a motion for summary judgment); *Johnson & Johnston*, 285 F.3d at 1054 (decided on summary judgment). Given that the Court does not have the benefit of a more developed record, analysis of the application of the disclosure-dedication rule is not appropriate at this stage of the litigation. Accordingly, Defendants' motion to dismiss is denied as to this issue.

CONCLUSION

For the reasons and to the extent stated above, EVER's motion to dismiss [84] is granted in part and denied in part, SHC and MCE's motion to dismiss [86] is granted in part and denied in part, and Ruyuan's motion to dismiss [96] is granted in part and denied in part.

Dated: February 27, 2025

Sunil R. Harjani
United States District Judge